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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,295	08/22/2003	Michael Ejstrup Hansen	6260.200-US	9216

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EXAMINER

NICOLAS, FREDERICK C

ART UNIT PAPER NUMBER

3754

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,295

Applicant(s)

HANSEN ET AL.

Examiner

Frederick C. Nicolas

Art Unit

3754

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/03&3/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The abstract of the disclosure is objected to because of legal phraseology "comprising" as recited in line 1, such terminology should be avoided in the abstract. Correction is required. See MPEP § 608.01(b).

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the claimed subject matter in claim 1, "a dose setting and injection part" as recited in line 1, "a piston rod" as recited in line 2, "a membrane" as recited in line 4, "a hollow needle" as recited in lines 5-6, and the claimed subject matter in claim 2, "at least one axial element" as recited in line 2, "an inward protrusion" as recited in line 3, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement

Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is replete with informalities, too numerous to mention specifically and failing to conform with U.S. Patent Office practice. The claim appears to be a literal translation into English from a foreign document. The following noted informalities are merely exemplary thereof. The claims should be revised to conform to U. S. Patent Office practice. Applicant is advised to completely review the claims for errors as the following is not intended to cover all errors.

I- As to claim 1, lines 3-4, it is unclear by what is meant by "to press a piston closing said first end of the cartridge into the cartridge".

II- As to claim 1, line 6, it is unclear by what is meant by "it pierces said membrane".

III- As to claim 1, the claimed limitation "a cartridge" as recited in line 2, and "a cartridge" as recited in claim 1, line 11 and lines 13-14, are vague and unclear because

it is not clear if the claimed limitation in line 11 and lines 13-14, "a cartridge" is the same as the claimed limitation noted in line 2 above. Applicant should restructure the claimed language to prevent double inclusion throughout the claims.

IV- As to claim 1, the claimed limitation "closing element" as recited in line 10, and "closing element" as recited in claim 1, line 12, are vague and unclear because it is not clear if the claimed limitation in line 12, "closing element" is the same as the claimed limitation noted in line 10 above. Applicant should restructure the claimed language to prevent double inclusion throughout the claims.

V- As to claim 4, lines 5-6, it is unclear by what is meant by "their bios".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Sarnoff 3,144,178.

Sarnoff discloses an injection device as seen in Figure 3, which comprises a cartridge holder (10), a dose setting and injection part which set doses can be apportioned from a cartridge (12) in the cartridge holder as a piston rod (30) is successively moved into a first end of the cartridge to press a piston (24) closing the first end of the cartridge into the cartridge which has a second end closed by a membrane (18), whereby a liquid (34) stored between the piston and the membrane can

be pressed out through a hollow needle (20) which is mounted on the device so that it pierces the membrane, access to the cartridge holder being obtained by opening a first end thereof through which the first end of the cartridge can be inserted with the piston facing the piston rod which extends into the cartridge holder from a second end thereof as seen in Figure 8, at least one closing element (50) is provided at the first end of the cartridge holder which closing element in its closed position forms a support for the second end of the cartridge to bar for an axial movement of the cartridge out of the cartridge holder and which the closing element is displaceable in a radial direction relative to the cartridge holder so that the closing element can be moved to a position allowing the cartridge to pass axially into or out of the cartridge holder (col. 2, ll. 19-49).

Allowable Subject Matter

7. Claims 2-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Holm et al. 4,973,318, Ma 4,314,556, Thorne et al. 6,036,675, McWethy et al. 6,752,798, Stiehl et al. 5,496,286, Knight 3,556,099 and Simmons 3,880,162 disclose other types of injection device.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick C. Nicolas whose telephone number is (703)-


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305-6385. The examiner can normally be reached on Monday - Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mancene L. Gene, can be reached on 703-308-2696. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FN
September 10, 2004

 9/10/04
Frederick C. Nicolas
Patent Examiner
Art Unit 3754